



GENAPP.002RA

(020728.0100)

PATENT

Applicant : Gopal)

Group Art Unit: 1636

Reissue Appl. : 09/404,979)

Filed : September 22, 1999)

For : PEPTIDE-MEDIATED)
GENE TRANSFER)

Examiner : McKelvey, T.)

SUPPLEMENTAL RESPONSE

In accordance with 37 C.F.R. §§ 1.313(c) and 37 C.F.R. § 1.114, Applicant submits herewith a request for continued examination (RCE), including (1) an Information Disclosure Statement citing, *inter alia*, U.S. Patent No. 6,150,168 to Woo et al. ("the '168 patent"), a reference not previously cited in the above-identified application. The '168 patent is related to U.S. Patent No. 5,994,109 ("the '109 patent"), a reference cited by the Examiner and addressed by Applicant during examination of the above-identified application. Applicant believes that the claims of the '168 patent could affect the patentability of the claims of the above-identified application and therefore submits this Supplemental Response and accompanying Declarations to address the limitations of the claims of the '168 patent.

The above-identified application is a reissue application of U.S. Patent No. 5,670,347, filed as application Serial No. ("SN") 240,514 on May 11, 1994 ("the Gopal patent"), which has an effective filing date of May 11, 1994. The subject matter claimed in the application is directed to a transfection vector comprising a synthetic polypeptide linked electrostatically to a DNA structural sequence, wherein the polypeptide comprises (A) a polymeric chain of basic

amino acid residues, (B) a nuclear localization signal (NLS) peptide and (C) a hinge region of neutral amino acids that connects the polymeric chain and the NLS peptide.

During prosecution of the above-identified application, the Examiner and the Applicant had discussions with regard to U.S. Patent No. 5,994,109 to Woo et al. ("the '109 patent"). In light of these discussions, the Applicant was able to overcome any potential rejection over the '109 patent by distinguishing the inventive "hinge region" of the above-identified application from the "spacer" employed in the '109 patent. This is evidenced by an Examiner Interview Summary Record dated December 19, 2000, an Examiner Interview Summary Record dated January 22, 2001, and the fact that the Examiner allowed the application.

Woo et al. obtained additional patents related to the '109 patent, including U.S. Patent No. 6,150,168 ("the '168 patent"). Although the '168 patent, which like the '109 patent, is a divisional of application SN 08/167,641, and thus has the same disclosure as the '109 patent, the '168 patent contains claims to "a hinge region," including claims to "a hinge region... comprised of glycine and serine." See the '109 patent at claims 36, 37, 39 and 40. Both of the above-mentioned Woo et al. patents stem from application SN 07/855,389, filed March 20, 1992. Thus, the earliest possible effective filing date is March 20, 1992.

Applicant submits a Declaration of Willy Wriggers, Ph.D. and a Declaration of Patricia A. Jennings, Ph.D., two experts in the analysis of protein and peptide structure, to attest to the state of the art at the effective filing dates of the Woo et al. patents and of the Gopal patent. As demonstrated in the attached Declarations, the terms "spacer" and "hinge" are used in a highly specific and mutually exclusive manner in the art; namely (a) spacers have extended structures permitting them to hold attached functional moieties in fixed spatial positions while (b) hinges are flexible regions that allow large movements of one attached moiety relative to another

attached moiety. Thus, the $[(\text{gly})_i(\text{ser})_j]_k$, wherein $i=1-6$; $j=1-6$; and $k=3-20$, spacer disclosed at col. 9, lines 4-29, of the '168 patent, as well as the remaining molecules defined as spacers in the '168 patent do not anticipate or render obvious the present claims, which are directed to hinge regions.

In light of the remarks and Declarations, early consideration and prompt allowance of the pending claims are respectfully requested.

By: Laura Donnelly 913102
Laura Donnelly
Registration No. 38,435

Patton Boggs LLP
8484 Westpark Drive
Ninth Floor
McLean, VA 22102
(703) 744-8030 (direct)
(703) 744-8001 (facsimile)
ldonnelly@pattonboggs.com